

Product PN 1222267, 1221008, 1224492, 1223340, 1242278

Mod. 984

Description 1.2 µm Polyethersulfone Filtration Membrane Discs and Sheets

Rev. 01

1.2 µm Polyethersulfone (PES) Filtration Membrane Discs and Sheets

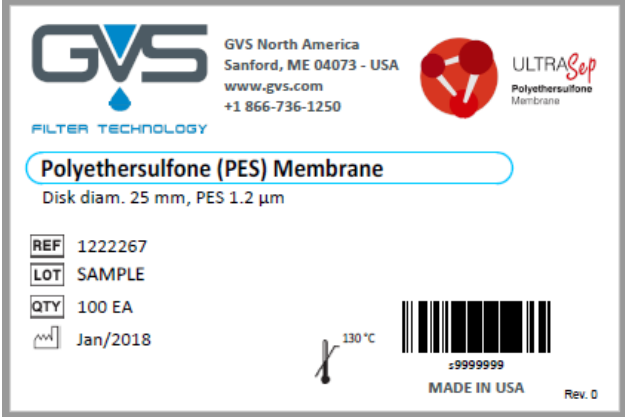


PRODUCT DESCRIPTION	1.2 µm PES Discs and Sheets			
	Part Number	Geometry	Dimensions	Packaging
	1222267	Disc	25 mm	100/Pk
	1221008	Disc	47mm	100/Pk
	1224492	Disc	90 mm	25/pk
	1223340	Sheet	200 x 200 mm	5/pk
	1242278	Sheet	30 cm x3 m	1/pk
MANUFACTURE NAME	<p>GVS North America, Inc. 63 Community Drive Sanford, ME 04073 Phone: +1.866.736.1250 Email: CustomerCareGVSLs@gvs.com Website: www.gvs.com</p>			
INTENDED USE/ APPLICATION	<p>Typical Applications:</p> <ul style="list-style-type: none"> • Environmental water studies • Industrial water filtration • IV filters • IV drug delivery • TPN delivery 			
MATERIALS	<p>Film: Polyethersulfone (PES)</p> <p>Regulatory Documentation Required:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Biocompatibility according to ISO 10993-1 <input type="checkbox"/> IMDS <input checked="" type="checkbox"/> RoHS, directive 2002/95/CE <input checked="" type="checkbox"/> BSE/TSE, directive 2003/32/CE <input type="checkbox"/> DEHP plasticizer and latex free <input type="checkbox"/> Aging <input checked="" type="checkbox"/> REACH 1907/2006/CE (hazardous substances regulation) <input type="checkbox"/> Dir. 67/548/CE and Reg. 1272/2008/CE (medical sector dangerous substances) <input checked="" type="checkbox"/> Conflict minerals <input checked="" type="checkbox"/> USP Class VI 			
PRODUCT CHARACTERISTICS	<ul style="list-style-type: none"> • USP Class VI compliant • Hydrophilic • Autoclavable • Broad sealing compatibility, including, ultrasonic, heat, radio frequency and insert molding • Metal Ions, Chloride and Sulfates: Not detectable (Analytical screen by ICP) 			

PRODUCT SPECIFICATION

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PRODUCT SHELF LIFE	5 years in normal storage conditions: Store the product at room temperate, in a dry place, free of dust and not exposed to direct sunlight.
STERILIZATION	This is a non-sterile product, compatible with these sterilization techniques*: <input checked="" type="checkbox"/> EtO <input checked="" type="checkbox"/> Gamma (25 kGy) <input checked="" type="checkbox"/> Autoclave (121°C) <input checked="" type="checkbox"/> eBeam <i>*user has the responsibility to validate their process</i>

PACKAGING AND LABELING	<table border="1"> <thead> <tr> <th>Product</th> <th>Interior package</th> <th>Exterior package</th> </tr> </thead> <tbody> <tr> <td>25, 47 mm Discs</td> <td>Discs separated by blue paper in a thermoformed tray</td> <td>Clear/white plastic box</td> </tr> <tr> <td>90 mm Disc</td> <td>Discs separated by blue paper</td> <td>Round container</td> </tr> <tr> <td>200 x 200 mm sheet</td> <td>Sheets separated by blue paper</td> <td>White mailer</td> </tr> <tr> <td>30 cm x 3 m</td> <td>Single sheet wrapped on a plastic core</td> <td>Cardboard box</td> </tr> </tbody> </table>	Product	Interior package	Exterior package	25, 47 mm Discs	Discs separated by blue paper in a thermoformed tray	Clear/white plastic box	90 mm Disc	Discs separated by blue paper	Round container	200 x 200 mm sheet	Sheets separated by blue paper	White mailer	30 cm x 3 m	Single sheet wrapped on a plastic core	Cardboard box
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<ul style="list-style-type: none"> Each configuration will be labeled with: <ul style="list-style-type: none"> Quantity Product item code and description Manufacturing date Lot number Storage conditions <p>Example label below:</p> 																

CERTIFICATE OF COMPLIANCE	A conformity declaration will be sent to the customer for each shipment with lot number and date of manufacture. The Quality management system is in compliance with ISO 9001.
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PERFORMANCE REQUIREMENTS	Acceptance Requirement		Standard Test Method	
	1	Thickness	110-150 µm	N/A
	2	Water Flow Rate	Min 98 mL/min/cm ² @ 10 psi	ASTM F 316-03




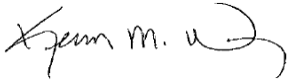
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	3	Bubble Point	11-22 psi (0.7-1.5 bar)	ASTM F 316-03
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This material specification describes the properties of product above indicated.
 This document contains general requirements, material description, drawing references, defect specification, and biological material requirements.

REVISIONS AND APPROVALS:

DATE	REV	REASON FOR CHANGE	ISSUED AND CONTROLLED BY: (name /function and signature)	APPROVED BY: (name /function and signature)
6/8/18	0	Initial Release	Gil Tavares/Process Development Engineer 	Kevin Wrigley/Director of Quality 

CUSTOMER APPROVAL:

We accept this material specification as a part of the agreed terms of delivery.

Company name _____

Approved by: _____
 (Name, Function) (Signature)

Date _____
 (Company stamp)

Please send back this document signed for approval. If we will not receive this specification signed, we consider the first order placed as implicit approval.